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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,032	09/29/2000	Joseph K. Agyin	6643R5	3249

30113 7590 09/17/2003

THE PROCTER AND GAMBLE COMPANY
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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	17

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/676,032	AGYIN ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-11,13-15,20 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-11,13-15,20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

The following is responsive to Applicant's amendment received May 9, 2003.

No claims are cancelled. No new claims are added. Claims 1-4, 7-11, 13-15, 20 and 25 are currently pending.

In view of the following new ground of rejection, the finality of the office action mailed March 17, 2003 is withdrawn. Prosecution on the merits is reopened.

Applicant's arguments traversing the previous rejection under 35 USC 103(a) maintained in the office action mailed March 17, 2003 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office actions mailed Aug. 27, 2002 and March 17, 2003 with the following additional comment:

It is Applicant's position that one of ordinary skill in the art would not know which piece of information to believe in the Ram et al. article, specifically referring to the statement on page 543, column 1 and the data for compound #17 in Table 1. Applicant contends that the only information regarding fluoro derivatives of phenyl esters is the data for the carboxamide derivatives 28 and 29 of Table III. Given the varying results of the compounds 28, 29 as well as 36, 37 38, Applicant argues that, at best, the disclosure of Ram et al. encourages an "obvious-to-try" standard which is an improper test for obviousness. Applicant argues that the teaching for making the structural and chemical changes to compound #17 necessary to resolve the differences in the claimed invention is absent in Ram et al.

Said arguments have been considered but are, respectfully, not found to be persuasive.

The Examiner respectfully submits that conclusory statements regarding the false information in Ram et al. are unconvincing unless supported by facts. It is also respectfully submitted that the compounds referred to by Applicant in the response are not the compounds used to reject the claims in the office action mailed August 27, 2002. It is not clear how Applicant's arguments with respect to these compounds serve to distinguish the claimed compounds and compositions from Ram's disclosure of compound #17. Furthermore, with respect to Applicant's assertion that the teachings of Ram et al. create an "obvious-to-try-" standard, the Examiner respectfully disagrees. Ram et al, first column, under Antitumor Results and Discussion, lines 1-8, disclose that all compounds in Table 1, "except for 13 and 18 showed cytotoxic activity against L1210 cells." Therefore, the Examiner respectfully maintains that such a disclosure suggests to one of ordinary skill in the art that compound #17 has antineoplastic activity. Therefore, modification of the compound of Ram to substitute the fluorine with a hydrogen would have been obvious to one of ordinary skill in the art because, absent **evidence** to the contrary, such a substitution would not be expected to materially alter the anti-neoplastic activity of the compound. This is further evidenced by the fact that both Applicant's compound and the claimed compound have the same activity. Therefore, the Examiner respectfully maintains that the claimed compound and the compound of Ram share close structural similarity and one of ordinary skill in the art would reasonably expect the two compounds to have similar antineoplastic activity.

It is for these reasons that the rejection is maintained.

Claim Rejection—35 USC 112

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a pharmaceutical kit for treating cancer or a viral infection in a warm-blooded animal.

(2) The state of the prior art

Concerning the treatment of viral infections, the art recognizes the presence of several types of viruses, i.e. DNA viruses and RNA viruses, each of which function differently. According to Goodman & Gilman's, effective antiviral agents have a limited spectrum of activity and target a specific viral protein (please see page 1192; lines 13-

16 of the left column). Therefore, an "antiviral" agent effective against herpes would not necessarily treat an HIV infection.

With respect to cancer, this a broad term which encompasses numerous forms of neoplastic diseases, each involving different types of tissues and organs. As recognized in the art, many different antineoplastic drugs are used to treat a variety of cancers, but there is no one drug which is capable of treating all cancers in general. Please see pages 1226-1229 of Goodman & Gilman's.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are very broad and encompass treatment of a viral infection and cancer in general.

(6) The amount of direction or guidance presented

Applicant's specification does not appear to provide guidance for the treatment of viral infections, which may encompass both DNA and RNA viruses (please see page 8, lines 14-16). The specification provides no guidance, to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous viral infections. Furthermore, the specification appears to only be enabled for the treatment of carcinomas such as colon and melanoma tumor cells. It does not enable one of ordinary skill in the art to use the

claimed invention in the treatment of the numerous neoplastic diseases covered by the term "cancer." In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of the claimed compounds which have antiviral activity and which would be capable of treating different kinds of viral infections. Moreover, other than the examples involving carcinomas, Applicant has not set forth a representative number of examples of cancers, which would be treated by the claimed compounds.

(7) The presence or absence of working examples

There are no working examples, in vivo or in vitro, in the specification relating to the treatment of viruses.

The only working examples in the specification involve the use of colon and melanoma tumor cells and a microtubule inhibition assay.

(8) The quantity of experimentation necessary

Since (1) antivirals have a restricted spectrum of antiviral activity; (2) no one compound is capable of treating the numerous neoplastic diseases encompassed by the term "cancer"; and (3) since compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, one of

ordinary skill in the art would be burdened with undue experimentation to determine which of the many cancers would be treated by the claimed compounds, and which compounds would have antiviral activity as well as the viruses against which the claimed compounds would be effective.

Conclusion

Claim 25 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Sept. 9, 2003

D[illegible]S
PR[illegible] EXAMINER